REMARKS

Claims 1-23 were previously cancelled. By this Amendment, Applicant has cancelled previously withdrawn claims 35-46. New claims 51-57 have been added. No new matter has been added to this application. Thus, claims 24-34 and 47-57 are pending and under consideration.

Claim 24 has been amended to recite a distal tip including a plurality of distally located apertures. New claims 51-57 further define the distal tip and the plurality of apertures of the distal tip. Support for these amendments can be found throughout the as filed specification and drawings, including for example, Fig. 5 and paragraphs 16, 18, and 46-50 of the corresponding published application (U.S. Patent Application Publication No. 2004/0098105). Accordingly, no new matter has been added.

35 U.S.C § 102(e) Rejection

The present '570 application is generally directed, for example, to methods and devices for draining pseudocysts. See generally specification, page 1. Pseudocysts can occur within the abdominal cavity or peritoneal cavity as a result of a build up of tissue, fluid, debris, pancreatic enzymes and/or blood. In one aspect, the '570 application describes a stent delivery system for implanting a stent within the gastric or abdominal wall to facilitate draining of a pseudocyst. *Id.* The stent can be a self-expandable stent adapted to drain a gastric pseudocyst when implanted and having a diameter when expanded that is larger than the diameter of an individual endobiliary tube. *Id.* As described in the present specification, endo-biliary tubes were previously used to drain pseudocysts, but had certain drawbacks including the need to implant

multiple endobiliary tubes and the tendency of the tubes to become blocked or partially obstructed. *Id.*

The Office rejects claims 24, 26-28, 30, 31, and 33 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,458,092 to Gambale et al. ("Gambale"). See Office Action, page 2. With respect to independent claim 24, the Office maintains that:

> Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter.

Office Action at p. 2.

Applicants respectfully disagree with and traverse this rejection, at least because Gambale fails to suggest or disclose an endoscope or a distal tip including a plurality of distally located apertures, as claimed. See claim 24.

Claim 24 recites a stent delivery system that includes an endoscope that receives the outer catheter and is configured for intraoral introduction. Gambale does not disclose such an endoscope. Nor does the Office Action address this claim recitation. That is because Gambale is directed to angiogenesis implant devices that are implanted into cardiac tissue to foster the growth of blood vessels. See Gambale, col. 2, lines 35-51. The implants expand when implanted, irritating the surrounding tissue to promote an angiogenic response. Gambale, therefore, focuses on cardiac applications where an endoscope would be unusable. See Gambale, col. 5, lines 18-23. In particular, Gambale's implantable devices are configured for percutaneous access via a delivery catheter 36. See Gambale, Figs. 4A, 4B and col. 9, lines 18-30.

Conversely, an endoscope cannot be driven through a blood vessel and into a cardiac chamber as required by Gambale. Endoscopes are designed to permit access

via a natural body orifice, such as a trans-oral approach to the stomach. Moreover, an endoscope would not fit through a blood vessel.

Furthermore, the claimed endoscope houses the inner catheter, outer catheter, and stent. Thus, this system includes an additional outer structure that guides the outer catheter through a trans-oral approach and includes a passage for the outer catheter. Even if an endoscope could permit vascular access, which it cannot, their would be no reason to add an additional layer to the device of Gambale.

Gambale also fails to disclose or suggest a distal tip including a plurality of distally located apertures. Gambale's device would have no use for such apertures because the device includes sharpened distal tip 84, which is configured to pierce cardiac tissue. See Gambale, Figs. 9A, 9C and col. 14, lines 9-21. As such, Gambale's device has no need for an aperture "configured to receive the perforating means." See claim 24.

For at least the foregoing reasons, Gambale fails to teach or disclose each and every element of the system of claim 24. In particular, Gambale fails to disclose a distal tip including a plurality of distally located apertures and an endoscope for trans-oral delivery of the claimed stent. Accordingly, Applicants respectfully submit that the rejection of independent claim 24, and the claims dependent thereon, should be withdrawn.

35 U.S.C. § 103(a) Rejections

The Office rejects claims 24, 25, 29-31, 33, 47, 48 and 50 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,290,728 to Phelps et al. ("Phelps") in view of U.S. Patent No. 5,702,418 to Ravenscroft ("Ravenscroft"). Office Action at p. 3.

In particular, the Office alleges that Phelps discloses all the elements of independent claim 24 except for an "endoscope for receiving the outer catheter." *Id.* at 4. The Office also alleges that Ravenscroft discloses "a stent delivery device incorporating an endoscope[,]" and that it would have been obvious "to incorporate the use of an endoscope into the delivery device of Phelps[.]" *Id.*

Applicants respectfully disagree with and traverse this rejection at least because Phelps and Ravenscroft, taken alone or in combination, fail to teach or suggest each and every element of amended claim 24. Specifically, neither Phelps nor Ravenscroft teaches or suggests a stent delivery system that comprises, inter alia, a distal tip including a plurality of distally located apertures. See claim 24.

Accordingly, Applicants submit that the 35 U.S.C. § 103(a) rejection of claim 24 is improper and should be withdrawn. Because claims 25, 29-31, 33, 47, 48 and 50 depend from amended claim 24, Applicants respectfully submit that these claims are also patentable over Phelps in view of Ravenscroft.

The Office also rejects claims 24, 25-28, 30, 33, 34, 47, 48 and 50 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,599,315 to Wilson ("Wilson") in view of U.S. Patent No. 6,533,753 to Haarstad et al ("Haarstad"), further in view of Ravenscroft. Office Action at p. 5. In particular, the Office alleges that Wilson "does not disclose that the first guidewire is a perforating means that is a retractable needle." *Id.* The Office also alleges that Haarstad discloses "use [of] a stiff guidewire to penetrate lesions[,]" and that it would have been obvious "to incorporate the use of an endoscope into the delivery device of Wilson modified by Haarstad..." *Id.* at 5, 6.

Applicants respectfully disagree with and traverse this rejection, at least because Wilson, Haarstad, and Ravenscroft, taken alone or in combination, fail to teach or suggest each and every element of amended claim 24. Specifically, Wilson, Haarstad, and Ravenscroft do not teach or suggest a stent delivery system comprising, inter alia, a distal tip including a plurality of distally located apertures. See claim 24.

Accordingly, Applicants submit that the 35 U.S.C. § 103(a) rejection of claim 24 is improper and should be withdrawn. Because claims 25-28, 30, 33, 34, 47, 48 and 50 depend from amended claim 24, Applicants also respectfully submit that these claims are patentable over Wilson in view of Haarstad, further in view of Ravenscroft.

The Office also rejects claim 49 under 35 U.S.C. § 103(a) as unpatentable over Wilson in view of Haarstad and Ravenscroft, and further in view of U.S. Patent No. 6,165,209 to Patterson et al. ("Patterson"). Office Action at p. 7. In particular, the Office alleges that Patterson discloses "stents that are used in arteries to have a diameter from 4 to 10 mm." *Id.*

Applicants respectfully disagree with and traverse this rejection, at least because Wilson, Haarstad, Ravenscroft, and Patterson, taken alone or in combination, fail to teach or suggest each and every element of amended claim 24. Specifically, Wilson, Haarstad, Ravenscroft, and Patterson do not teach or suggest a stent delivery system comprising, inter alia, a distal tip including a plurality of distally located apertures. See claim 24.

Accordingly, Applicants submit that the 35 U.S.C. § 103(a) rejection of claim 24 is improper and should be withdrawn. Because claim 49 depends from amended claim

24, Applicants also respectfully submit that claim 49 is patentable over Wilson in view of Haarstad and Ravenscroft, further in view of Patterson.

Finally, the Office rejects claims 32 and 49 under 35 U.S.C. § 103(a) as unpatentable over Phelps in view of Ravenscroft, and further in view of U.S. Patent No. 5,674,276 to Anderson et al. ("Anderson"). Office Action at p. 8. In particular, the Office alleges that Anderson discloses "a biliary stent and stents used for shunts that fall within the claimed parameters." *Id.*

Applicants respectfully disagree with and traverse this rejection, at least because Phelps, Ravenscroft, and Anderson, taken alone or in combination, fail to teach or suggest each and every element of amended claim 24. Specifically, Phelps, Ravenscroft, and Anderson do not teach or suggest a stent delivery system comprising, inter alia, a distal tip including a plurality of distally located apertures. See claim 24.

Accordingly, Applicants submit that the 35 U.S.C. § 103(a) rejection of claim 24 is improper and should be withdrawn. Because claims 32 and 49 depend from amended claim 24, Applicants respectfully submit that these claims are also patentable over Phelps in view of Ravenscroft, and further in view of Anderson.

Conclusion

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 24-34 and 47-57 in condition for allowance. Applicants submit that the amendment to claim 24 and the newly added claims 51-57 do not raise new issues or necessitate the undertaking of any additional search of the art

by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

If the Examiner has any questions or concerns regarding this application, she is cordially invited to contact the undersigned attorney via telephone.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 29, 2008

By: _____
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